

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 9 1999

Matthew G. Kramer
Vice President, Product Development
Agritope, Inc.
16160 SW Upper Boones Ferry Road
Portland, Oregon 97224-7744

Dear Mr. Kramer:

This is in regard to Agritope's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its genetically modified cantaloupe, lines A and B. According to Agritope, these new lines are modified through fruit-specific expression of the transgene, *sam-k*. The *sam-k* gene encodes the S-adenosylmethionine hydrolase (SAMase) enzyme, which confers a modified fruit ripening phenotype.

As part of bringing the consultation regarding these products to closure, Agritope submitted a summary of its safety and nutritional assessment of the genetically modified cantaloupe lines on May 5, 1999. This communication informed the FDA of the steps taken by Agritope to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Agritope has conducted, it is our understanding that Agritope has concluded that cantaloupes derived from these new varieties, are not materially different in composition, safety, and other relevant parameters from cantaloupes currently on the market and that the genetically modified cantaloupes do not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF 0060. This file will be maintained in the Office of Premarket Approval.

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Based on the information Agritope has presented to FDA, we have no further questions concerning cantaloupe from lines A and B at this time. However, as you are aware, it is Agritope's continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition